REMARKS

This is a response to the Office Action dated June 26, 2002. Claims 1, 2, 4, 5, 8-18, 20-22 and 24-35 are pending in this application. Claims 1-6 and 8-23 have been rejected by the Examiner. As noted above, Applicants have canceled 3, 6, 7, 19 and 23 without prejudice, have amended Claims 1, 2, 5, 8, 13, 17, 18 and 20-22, and added new Claims 24-35. The amendments and new Claims 24-35 are fully supported by the written description. No new matter has been introduced into the application. The numbered paragraphs below correspond to the Examiner's numbered paragraphs in the Office Action:

1.-7. Applicants affirm election of Group I, Claims 1-6 and 8-23. Claim 7 has been canceled without prejudice.

8./9. The Examiner has rejected Claims 22 and 23 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has found that the term "warm" is a relative term. Claim 22 has been amended and recites in part, "a temperature greater than ambient temperature." As a result of the amendment, Applicants believe that Claim 22 has overcome the rejection. Claim 23 has been canceled without prejudice.

10./11. Claims 1-4 have been rejected under 35 U.S.C. §102(b) as being anticipated by Jayaraman (USPN 5,891,507). Jayaraman discloses a method in which "a metallic stent is manufactured in a known manner and is then cleaned to remove surface contaminants and carbon deposits formed from cutting operations and electro-polishing procedures" (abstract). Jayaraman further discloses that

> after the stent has been suitably polished, it is placed in a bath of deionized water. The water is then heated to boiling temperature and the stent is retained therein for from fifteen minutes to forty-five minutes. Thereafter, the stent is removed from the bath and placed in a sealed chamber in which nitrogen gas is purged. The chamber is kept at a temperature within the range of 40°C. to 80°C. and at a pressure in the range of 2 psi to 14 psi. This drying step is carried out for a period of eight to twelve hours. **Thereafter, the stent is removed from the sealed chamber and placed in a bath containing a**

> **suitable surfactant that is intended to remove all residual carbon that might still be present on the stent surfaces**

(col. 3, lines 18-30) (emphasis added). Then Jayaraman discloses that the "next process step in the inventive process involves coating the stent 10 by immersing it in a coating material exposed to ultrasonic energy" (col. 3, lines 48-50).

Jayaraman does not disclose, or even hint, that the stent is **maintained at a temperature greater than ambient temperature after the stent is removed from the sealed chamber** during the drying step. In particular, Jayaraman does not disclose that stent is at **a temperature greater than ambient temperature in either the surfactant bath step, or the coating step**. Therefore, at a minimum, Jayaraman does not disclose "**increasing the temperature of the stent to a temperature greater than ambient temperature**; applying a coating substance onto the stent after the increasing step; and **maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step**" as recited by Claim 1. Accordingly, Claim 1 is allowable over Jayaraman. Claims 2 and 4 depend directly from Claim 1, and are allowable for at least the same reason. Claim 3 has been canceled without prejudice. Withdrawal of the rejection and allowance of the claims are respectfully requested.

12. Claims 1, 3-5, 11 and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by Fan et al. (USPN 5,558,900). Fan et al. disclose a method of coating a catheter in which the coating is "applied by a solution coating process, such as dip coating, roller coating, spray coating" (col. 4, lines 32-33). Then the wet catheter is "dried to remove the solvent e.g., by heating in a convection oven. A heating temperature of between about 30 to about 150 degrees centigrade, and a heating time of from about one minute to several hours may be used depending on the material of construction of the catheter" (col. 4, lines 41-47). Fan et al. additionally disclose an exemplary procedure where

> (1) the coating solution was drawn into the catheter, which is being held vertically above the solution bath, using a suction device such as a syringe and held for 5 minutes; (2) the

> catheter is subsequently turned upside down to drain the coating solution; and (3) the catheter was dried by blowing preheated hot air at about 75 degrees centigrade through the opening of one end of the catheter while the whole catheter is wound was a coil shape and placed in an oven at 75 degrees centigrade

(col. 16, lines 20-29).

Fan el al. fail to disclose a method of coating a stent including, "increasing the temperature of the stent to a temperature greater than ambient temperature; applying a coating substance onto the stent after the increasing step; and **maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step**" as recited by Claim 1. At a minimum, Fan et al. fail to disclose a method of coating a stent. Also, Fan et al. disclose that the catheter is exposed to hot air **after** the coating solution has been applied to the catheter. Therefore, Fan et al. do not disclose that the temperature of the stent is increased **before** application of the coating solution, nor do they disclose "**maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step.**" Accordingly, Claim 1 is allowable over Fan et al. Claim 4 depends directly from Claim 1, and is allowable for at least the same reason. Claim 3 has been canceled without prejudice.

With respect to Claim 5, Fan et al. fail to disclose a method of coating a stent including, "applying a composition including a fluid onto an stent; directing a gas with a temperature greater than ambient temperature onto the stent subsequent to the application of the composition to induce evaporation of at least a portion of the fluid from the composition; and repeating the acts of applying and directing to form multiple layers of the composition on the stent." As noted above, Fan et al. fail to disclose a method of coating a stent. In addition, Fan et al. do not disclose that the hot air, for example as described in Examples 71-73 of Fan et al. (col. 16, lines 13-40), is applied "to induce evaporation **of at least a portion of the fluid** from the composition." Finally, Fan et al. fail to disclose that they repeat the acts of applying the coating solution and directing the hot air "to form multiple layers of the composition on the stent."

Instead, Fan et al. blow the preheated hot air onto the catheter to dry the coating solution as part of a final step. Accordingly, Claim 5 is allowable over Fan et al. Claims 11 and 14 depend directly from Claim 5, and are allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims are respectfully requested.

13. Claims 5, 8, 14-16, 19 and 20 have been rejected under 35 U.S.C. §102(b) as being anticipated by Zhong et al. (USPN 6,156,373). Zhong et al. is directed to "[d]evices and methods for applying a polymeric coating to a medical device. The steps of the coating process including applying a liquid polymeric material to the surface of the medical device, then directing a stream of gas to impinge on the surface of the medical device" (abstract). Zhong et al. disclose that

> The flow of gas through the openings and around the wires of the stent is sufficient to displace excess coating solution, any lumps, fibers, etc. formed by the coating solution and will be blown off the surfaces of the stent by the gas stream. Once the excess coating solution has been removed from the surfaces of the stent, the solvent of the coating solution is allowed to evaporate, thereby leaving on the surface of the stent, a polymer coating

(col. 4, lines 47-55).

Zhong et al. fail to disclose a method of coating a stent including, "applying a composition including a fluid onto an stent; **directing a gas with a temperature greater than ambient temperature** onto the stent subsequent to the application of the composition to induce evaporation of at least a portion of the fluid from the composition; and **repeating the acts of applying and directing to form multiple layers of the composition on the stent**" as recited by Claim 5. In particular, Zhong et al. at least do not disclose that the gas is at "**a temperature greater than ambient temperature.**" Furthermore, Zhong et al. do not disclose or suggest a step that includes "**repeating the acts of applying and directing to form multiple layers of the composition on the stent.**" Accordingly, Claim 5 is allowable over Zhong et al. Claims 8, 14-16 and 20 depend directly or indirectly from Claim 5, and are allowable for at least the same

reason. Withdrawal of the rejection and allowance of the claims are respectfully requested. Claim 19 has been canceled without prejudice.

14./15. Claims 12 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fan et al. As indicated above, Claim 5 is allowable over Fan et al. Claims 12 and 13 depend directly from Claim 5, and are allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims are respectfully requested.

16. Claims 6, 9-13, 17, 18, 22 and 23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zhong et al. As indicated above, Claim 5 is allowable over Zhong et al. Claims 6, 9-13, 17 and 18 depend directly or indirectly from Claim 5, and are allowable for at least the same reason.

With respect to Claim 22, Zhong et al. fail to disclose a method of coating a stent including,

> applying a gas with a temperature greater than ambient temperature onto the stent for a duration of about 1 second to about 100 seconds to remove at least a portion of the solvent from the composition; and repeating the acts of spraying and applying to form multiple layers of the composition.

In particular, Zhong et al. at a minimum do not disclose "applying a gas with a **temperature greater than ambient temperature** onto the stent," nor do they disclose that the gas is applied "**for a duration of about 1 second to about 100 seconds** to remove at least a portion of the solvent." Zhong et al. also do not disclose or suggest that the method should include "repeating the acts of spraying and applying to form multiple layers of the composition." Accordingly, Claim 22 is allowable over Zhong et al. Claim 23 has been canceled without prejudice. Withdrawal of the rejection and allowance of the claims are respectfully requested.

17. Claims 22 and 23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zhong et al. in view of Fan et al. As indicated above, Claim 22 is allowable over Zhong et al. Fan et al. do not cure the previously described deficiencies of Zhong et al. with

respect to Claim 22. In particular, Fan et al. at a minimum do not disclose a method for coating a stent, nor do they disclose that the gas is applied "**for a duration of about 1 second to about 100 seconds** to remove at least a portion of the solvent." Fan et al. also do not disclose or suggest that the method should include "repeating the acts of spraying and applying to form multiple layers of the composition." Accordingly, Claim 22 is allowable over Zhong et al. in view of Fan et al. Withdrawal of the rejection and allowance of Claim 22 is respectfully requested. Claim 23 has been canceled without prejudice.

18. Claim 1-4 and 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zhong et al. in view of Pham et al. (USPN 6,358,567). Pham et al. is directed to a method that "is particularly useful for depositing ceramic coatings. Dense ceramic coating materials on porous substrates are useful in providing improved electrode performance in devices such as high power density solid oxide fuel cells. Dense ceramic coatings obtained by the invention are also useful for gas turbine blade coatings, sensors, steam electrolyzers, etc." (abstract).

To establish *prima facie* obviousness, **all of the claimed limitations** must be taught or suggested in the references cited. In re Royka, 490 F.2d 981 (CCPA 1974). Zhong et al. and Pham et al., alone or in combination, fail to teach or suggest all of the claimed limitations of Claim 1. In particular, Zhong et al. fail to teach or suggest at least, "**increasing the temperature of the stent to a temperature greater than ambient temperature**; applying a coating substance onto the stent after the increasing step; and **maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step**." Although Pham et al. disclose that "prior to deposition one step of the method involves heating the substrate close to or above the boiling point of the solvent" (col. 4, lines 31-33), Pham et al. fail to teach or suggest that the method includes "**maintaining the temperature of the stent at a**

temperature greater than ambient temperature during the applying step" as recited by Claim 1. Accordingly, Claim 1 is allowable over Zhong et al. in view of Pham et al.

In addition, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Zhong et al. with the teachings of Pham et al. in order to make the claimed invention. There are three possible sources for a motivation to combine references: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998). However, the mere fact that a prior art reference can be modified does not make the modification obvious unless the prior art also suggests the desirability of the modification. See In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). Zhong et al. disclose that

> The flow of gas 904 around struts 824 and body member 822 is sufficient to displace excess coating solution. Once the excess coating solution has been removed from or redistributed on the surfaces of thrombosis filter 820, the solvent in the coating solution is allowed to evaporate thereby leaving on the surface of thrombosis filter 820 a polymer coating, which preferably includes a therapeutic agent. **Because all imperfections were removed before the coating solution was allowed to dry, the polymer coating resulting from this process is evenly distributed across the surfaces of thrombosis filter 820**

(col. 14, lines 10-20) (emphasis added). The above quotation from Zhong et al. indicates that Zhong et al. teach that the coating solution should not be evaporated until after the gas displaces the excess coating solution. As a result, Zhong et al. teach away from "increasing the temperature of the stent to a temperature greater than ambient temperature" and "maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step" as recited by Claim 1. Therefore, there would have been no suggestion or motivation to modify Zhong et al. with the teachings of Pham et al., in particular, "heating the substrate close to or above the boiling point of the solvent."

Additionally, as indicated above, Claim 5 is allowable over Zhong et al. Pham et al. do not cure the previously described deficiencies of Zhong et al. with respect to Claim 5. Accordingly, Claim 5 is allowable over Zhong et al. in view of Pham et al. Claim 21 depends on Claim 5, and is allowable for at least the same reason. Withdrawal of the rejection and allowance of Claim 21 is respectfully requested.

CONCLUSION

Claims 1, 2, 4, 5, 8-18, 20-22 and 24-35 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

Date: October 24, 2002

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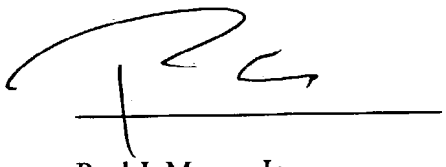
Respectfully submitted,



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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the Claims as indicated below. The Italicized claims have not been amended and are provided for the Examiner's convenience.

1. (Amended) A method of coating ~~an implantable device~~**a stent**, comprising **the steps of**:

~~adjusting~~**increasing** the temperature of the ~~implantable device~~**stent** to a temperature ~~other~~**greater** than ambient temperature; ~~and~~

applying a coating substance ~~to the implantable device~~**onto the stent after the increasing step; and**

maintaining the temperature of the stent at a temperature greater than ambient temperature during the applying step.

2. (Amended) The method of Claim 1, wherein the ~~implantable device~~**stent** is ~~a~~ metallic ~~stent~~.

Please cancel Claim 3.

4. *The method of Claim 1, wherein the coating substance includes a polymer dissolved in a fluid and optionally an active agent.*

5. (Amended) A method of coating ~~an implantable device~~**a stent**, comprising the acts of:

applying a composition including a fluid ~~to~~**onto** ~~an implantable device~~**a stent**; ~~and~~

directing a gas ~~onto the implantable device~~**with a temperature greater than ambient temperature onto the stent subsequent to the application of the composition** to

induce evaporation of **at least a portion of** the fluid from the composition ~~**to form a coating on the implantable device; and**~~

repeating the acts of applying and directing to form multiple layers of the composition on the stent.

Please cancel Claims 6 and 7.

8. (Amended) The method of Claim 5, wherein the act of applying comprises spraying the composition onto the ~~**implantable device**~~**stent**.

9. *The method of Claim 8, wherein the act of spraying is performed at a flow rate of about 0.01 mg/sec to about 1 mg/sec.*

10. *The method of Claim 8, wherein the act of spraying is performed for a duration of about 0.5 seconds to about 5 seconds.*

11. *The method of Claim 5, wherein the temperature of the gas is about 25 ℃ to about 200 ℃.*

12. *The method of Claim 5, wherein the act of directing is performed for a duration of about 1 second to about 100 seconds.*

13. (Amended) The method of Claim 5, wherein the act of directing is performed at a flow ~~**speed**~~**rate** of about 0.01 m^3/second to about 1.42 m^3/second.

14. *The method of Claim 5, wherein the composition includes a polymer dissolved in the fluid and optionally an active agent.*

15. *The method of Claim 14, wherein the active agent is actinomycin D, paclitaxel, docetaxel, or rapamycin.*

16. *The method of Claim 5, wherein the composition additionally includes a radiopaque element or a radioactive isotope.*

17. (Amended) The method of Claim 5, additionally comprising rotating the ~~**implantable device**~~**stent** about the longitudinal axis of the ~~**implantable device**~~**stent**.

18. (Amended) The method of Claim 5, additionally comprising moving the ~~implantable device~~stent in a linear direction along the longitudinal axis of the ~~implantable device~~stent.

Please cancel Claim 19.

20. (Amended) The method of Claim ~~19~~5, wherein the stent is at least partially expanded during the acts of applying and directing.

21. (Amended) The method of Claim 5, additionally comprising heating the stent prior to the act of applying~~: heating~~ the ~~implantable device~~composition, wherein the temperature of the stent is increased to a temperature greater than ambient temperature and is maintained at a temperature greater than ambient temperature as the composition is applied to the ~~warm implantable device~~stent.

22. (Amended) A method of coating a stent, comprising the acts of:

spraying onto a stent a composition including a solvent, a polymer dissolved in the solvent, and optionally an active agent;

applying a ~~warm~~ gas with a temperature greater than ambient temperature onto the stent for a duration of about 1 second to about 100 seconds to remove at least a portion of the solvent from the composition ~~and form a coating on the stent~~; and

repeating the acts of spraying and applying to form multiple layers of the composition.

Please cancel Claim 23.

24. (New) The method of Claim 1, wherein the temperature that is maintained during application is about 35°C to about 80°C.

25. (New) The method of Claim 1, wherein the coating substance comprises an ethylene vinyl alcohol copolymer or poly-n-butyl methacrylate.

26. (New) The method of Claim 5, wherein the act of repeating is performed 2 to 41 times.

27. (New) The method of Claim 5, additionally including waiting for a period of about 0.1 seconds to about 5 seconds after application of the composition before directing the gas onto the stent.

28. (New) The method of Claim 5, wherein the composition comprises a polymer selected from the group consisting of an ethylene vinyl alcohol copolymer and poly-n-butyl methacrylate.

29. (New) The method of Claim 5, wherein during the act of applying about 1 microgram of composition per cm^2 of stent surface to about 50 micrograms of composition per cm^2 of stent surface is applied.

30. (New) The method of Claim 21, wherein the fluid is selected from the group consisting of dimethlysulfoxide, dimethylformamide, and dimethylacetamide and combinations thereof.

31. (New) The method of Claim 21, wherein the temperature that is maintained during application is 35°C to 80°C.

32. (New) The method of Claim 22, wherein the polymer comprises an ethylene vinyl alcohol copolymer or poly-n-butyl methacrylate.

33. (New) The method of Claim 22, additionally including waiting for a period of about 0.1 seconds to about 5 seconds after spraying of the composition before applying the gas onto the stent.

34. (New) The method of Claim 22, wherein the solvent is selected from the group consisting of cyclohexanone, ethyl acetate, choloform and methanol.

35. (New) A method of coating a stent, comprising the steps of:

adjusting the temperature of the stent to a temperature other than ambient temperature;

applying a coating substance onto the stent after the adjusting step; and

maintaining the temperature of the stent at a temperature other than ambient temperature during the applying step.

IN THE SPECIFICATION

Paragraph 22 beginning on page 7 has been amended as follows:

Each repetition can be followed by removal of a significant amount of the solvent(s). The removal of the solvent(s) can be performed following a waiting period of about 0.1 seconds to about 5 seconds after the application of the coating composition so as to allow the liquid sufficient time to flow and spread over the stent surface before the solvent(s) is removed to form a coating. The waiting period is particularly suitable if the coating composition contains a volatile solvent, such as solvents having boiling points ≥≤130°C at ambient pressure, since such solvents are typically removed quickly.

Paragraph 24 beginning on page 8 has been amended as follows:

In one embodiment, the stent can be warmed to a temperature of from about 35°C to about 80°C prior to the application of the coating composition so as to facilitate faster removal of the solvent(s). The particular temperature selected depends, at least in part, on the particular active agent employed in the coating composition. By way of example, pre-heating of the stent prior to applying a composition containing actinomycin D should be performed at a temperature not greater than about 55°C. Pre-heating is particularly suitable for embodiments in which the

solvent(s) employed in the coating composition has a high boiling point, i.e., less volatile solvents having boiling points of, for example, >130°C at ambient pressure (e.g., dimethylsulfoxide (DMSO), dimethylformamide (DMF), and dimethylacetamide (DMAC)).